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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,165

01/28/2004

James Matthew Stephens

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06/07/2006

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,165	STEPHENS, JAMES MATTHEW	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8,10-14 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8,10-14 and 19-21 is/are rejected.
- 7) ☒ Claim(s) 1-2, 4, 6-8, 10-14, 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-2, 4, 6-8, 10-14 and 19-21 are objected to because of the following informalities: In independent claims 1, 7 and 13, the full meanings for the abbreviations “BHAP, DBNPA, DTEA, DTEA II, MBT, ADBAC, TBTO, TCCBN, TCMTB, THPS, TKHPS and TTPC should be recited. In claim 21, the preamble “The matter of claim 7” should be changed to –The method of claim 7—since independent claim 7 recites a method. Appropriate correction is required.

2. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite since it is broader in scope than independent claim 7 from which it depends. In particular, the recited types of biocides recited in claim 11 are broader in scope than the particular biocides recited in independent claim 7. It is suggested to cancel claim 11 since claim 7 has now been amended to recite certain particular biocides.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-2, 4, 6-8, 10-14 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haddad (US 2004/0077106).

Haddad teaches of a synthetic urine and a method for making it. The synthetic urine comprises appropriate amounts of individual components of human urine such that the sample appears to be a genuine human urine. The synthetic urine comprises creatinine in normal levels, salts such as chlorides, phosphates and sulfates, and water to dilute the formulation. The synthetic urine has a specific gravity between about 1.00 and 1.035 g/cm³, and a pH between about 4 and 9. The urine can also include urea therein, and optionally a buffer to establish or maintain a pH of 4 to 9. Haddad teaches that a preservative can also be included in the artificial urine composition. The urine composition is preferably packaged in a sealed container such as a sealed pouch or airtight container. To form the urine composition, creatinine and salts are dissolved in water, and the resulting solution is stirred, shaken or mixed. Optional components of urea, a buffer and a preservative are also dissolved in the water. See paragraphs nos. 0012-0020 and 0024-0031 in Haddad. Haddad also teaches that a heat activator such as lithium bromide can be included in the synthetic urine composition. See paragraph no. 0033 in Haddad. While Haddad teaches that this material may be added to the composition for the purpose of being a heat activator, it also would inherently act as a biocide similar to the "bromides" recited in the instant claims that perform this function. Haddad fails to teach that the water used to make the synthetic urine has a pH between 3 and 10, and fails to teach that the preservative is present at a concentration that minimizes sepsis or bacterial growth in the synthetic urine.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the preservative in the synthetic urine composition taught by Haddad in a concentration that minimizes sepsis or bacterial growth since Haddad teaches that the synthetic urine is for the purpose of testing instrumentation used to analyze patient urine samples, and therefore, it must remain stable and free of bacterial growth and sepsis for a prolonged time period of time. It also would have been obvious to one of ordinary skill in the art to use water having a pH between 3-10 to make the synthetic urine taught by Haddad since Haddad teaches that the synthetic urine should have a pH between these values, and the use of water already having a pH in this range avoids the use of a buffer to establish the required pH level.

6. Claims 1-2, 4, 6-8, 10-14 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haddad in view of Dorn (US patent no. 6,716,632). For a teaching of Haddad, see previous paragraphs in this Office action. Haddad fails to teach of one of the biocides as specifically recited in the instant claims being included in the synthetic urine composition other than a bromide. Haddad also fails to teach that the water used to make the synthetic urine has a pH between 3 and 10.

Dorn teaches of a composition for preserving and transporting body fluids such as urine samples. The composition includes therein a biguanide biocide such as chlorhexidine. See lines 25-33 in column 4, lines 62-65 in column 9, lines 51-54 in column 15 and lines 54-57 in column 23 of Dorn that teach of the preservation of urine samples with a formulation that includes a biguanide biocide.

Based upon the combination of Haddad and Dorn, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a biocide such as the

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biguanide biocide taught by Dorn in the synthetic urine composition taught by Haddad since the synthetic urine composition of Haddad includes a preservative therein that typically acts to prevent the growth of microorganisms, and Dorn teaches that urine compositions should include a biocide such as a biguanide therein in order to prevent the growth of microorganisms. It also would have been obvious to one of ordinary skill in the art to use water having a pH between 3-10 to make the synthetic urine taught by Haddad since Haddad teaches that the synthetic urine should have a pH between these values, and the use of water already having a pH in this range avoids the use of a buffer to establish the required pH level.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Lynch et al who teach of a synthetic urine composition containing a bromide therein, i.e. potassium bromide. See Table III in column 5 of Lynch et al.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 1, 2006

Maureen M. Wallenhorst
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PRIMARY EXAMINER
GROUP ~~1700~~ 1700